



THE United States Senate  
**COMMITTEE on FINANCE**  
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For Immediate Release

May 06, 2012

Contact: Communications Office (Baucus), 202-224-4515

Jill Gerber (Grassley), 202-224-6522

## Baucus, Grassley Seek Answers about Opioid Manufacturers' Ties to Medical Groups

*Finance Leaders Investigate Whether Pharmaceutical Companies Encouraged Non-Profit Beneficiaries to Promote Misleading Information about Narcotic Painkillers*

Washington, DC – Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior Committee member Chuck Grassley (R-Iowa) initiated an investigation today into the connections of drug manufacturers Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson with medical groups and physicians who have advocated the increased use of narcotic painkillers, or opioids. The Senators also asked seven other medical groups to produce information about their financial ties and collaborations with opioid manufacturers. In letters sent to each yesterday, Baucus and Grassley requested documents and financial information from the companies and noted that deaths resulting from opioid overdoses have recently skyrocketed, growing nearly 400 percent between 1999 and 2008, the most recent year data was available. They also highlighted news reports suggesting the increase may be driven by misinformation and dubious marketing practices used by the pharmaceutical companies and the medical organizations they fund.

"Overdoses on narcotic painkillers have become an epidemic, and it's becoming clear that patients aren't getting a full and clear picture of the risks posed by their medications," Baucus said. "When it comes to these highly-addictive painkillers, improper relationships between pharmaceutical companies and the organizations that promote their drugs can put lives at risk. These painkillers have an important role in health care when prescribed and used properly, but pushing misinformation on consumers to boost profits is not only wrong, it's dangerous."

"The problem of opioid abuse is bad and getting worse," Grassley said. "Something has to change. A greater understanding of the extent to which drug makers underwrite literature on opioids is a good start. Doctors and patients should know if the medical literature and groups that guide the drugs' use are paid for by the drugs' manufacturers and if so, how much. Education on the proper use of pain medication is a key step in preventing abuse and misuse, so it's important to understand what material is out there."

The Centers for Disease Control and Prevention have declared overdoses from opioid painkillers to be a public health epidemic. Deaths from painkiller overdoses have tripled over the last decade and led to the deaths of 14,000 Americans in 2008, exceeding those caused by heroin and cocaine combined. The

### Related Files

-  Baucus Grassley Opioid Investigation Letter to Purdue Pharma (262.3 KB)
-  Baucus Grassley Opioid Investigation Letter to Federation of State Medical Boards (278.9 KB)
-  Baucus Grassley Opioid Investigation Letter to the Joint Commission (278.4 KB)
-  Baucus Grassley Opioid Investigation Letter to Wisconsin Pain And Policy Studies Group (277.5 KB)
-  Baucus Grassley Opioid Investigation Letter to American Academy of Pain Medicine (277.6 KB)
-  Baucus Grassley Opioid Investigation Letter to American Pain Foundation (278.8 KB)
-  Baucus Grassley Opioid Investigation Letter to American Pain Society (278.8 KB)
-  Baucus Grassley Opioid Investigation Letter to Center for Practical Bioethics (278.3 KB)
-  Baucus Grassley Opioid Investigation Letter to Johnson and

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**U.S. Senate panel launches investigation of painkillers, drug companies**  
By John Fauber of the Journal Sentinel May 9, 2012

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"Recent investigative reporting from the Milwaukee Journal Sentinel/Medpage Today and ProPublica revealed extensive ties between companies that manufacture opioids and non-profit organizations such as the American Pain Foundation....and the Joint Commission."

Letter to Endo Pharmaceuticals  
Letter to American Pain Foundation  
Letter to American Pain Society  
Letter to American Academy of Pain Medicine

**Side Effects**

U.S. Sens. Chuck Grassley (R-Iowa) and Max Baucus (D-Mont.).

The senators said there was growing evidence that drug companies have promoted misleading information about the safety and effectiveness of the drugs with help from nonprofits they have donated to.

"Recent investigative reporting from the Milwaukee Journal Sentinel/MedPage Today and ProPublica revealed extensive ties between companies that manufacture and market opioids and nonprofit organizations such as the American Pain Foundation, the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the University of Wisconsin Pain and Policy Studies Group and the Joint Commission," Grassley and Baucus wrote.

In addition to the pain organizations, the committee also sought records from three leading drug companies: Purdue Pharma, Johnson & Johnson and Endo Pharmaceuticals. It also requested records from the Center for Practical Bioethics, a Kansas City, Mo., organization that has advocated for pain treatment.

The committee said it wants records dating back to 1997.

The letter notes that a February Journal Sentinel/MedPage Today story

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Posted on Fri, May, 11, 2012 11:22 PM

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## Bioethics think tank's ties to pain pill industry studied

BY ALAN BAVLEY  
The Kansas City Star

A U.S. Senate committee is examining a Kansas City-based bioethics think tank's financial ties to the pain-pill industry.

The inquiry is part of a sweeping investigation by the Senate Finance Committee of connections between pain drug manufacturers and organizations and physicians who have advocated for increased use of narcotic — also known as opioid — painkillers.

Abuse of these potentially addictive pain medications has become a national epidemic and accounts for more overdose deaths than heroin and cocaine combined. About 5 million people had used the drugs recently without a prescription, a federal survey found.

The Center for Practical Bioethics is one of seven organizations that received letters this week from the Senate committee asking them for information about their financial ties and collaborations with opioid manufacturers.

The other organizations are the American Pain Foundation, the American Academy of Pain Medicine, the American Pain Society, the Wisconsin Pain and Policy Study Group, the Joint Commission of Accreditation of Healthcare Organizations and the Federation of State Medical Boards.

Recent investigations by news organizations have found that some of these groups, such as the American Pain Foundation, a patient advocacy group, are funded largely by the drug industry.

The Senate committee is seeking to determine whether any of the groups promoted misleading information about the risks and benefits of opioids while receiving financial support from manufacturers of the drugs.

A Senate aide told The Kansas City Star that the investigation may bring into question guidelines for pain management, or the legitimacy of some of the organizations under scrutiny.

One of the organizations, the American Pain Foundation, disbanded last week, citing "irreparable economic circumstances."

### Breaking News

Homers by Francœur and Butler lift Royals to 4-2 victory over Orioles

La Crosse, Kan., is cleaning up after twister

No injuries but much damage in Columbia apartment fire

Franchitti wins 3rd Indy 500, gives nod to Wheldon

Former KC Chief charged with attempted murder

Man, 65, shoots motorcyclist in road rage incident

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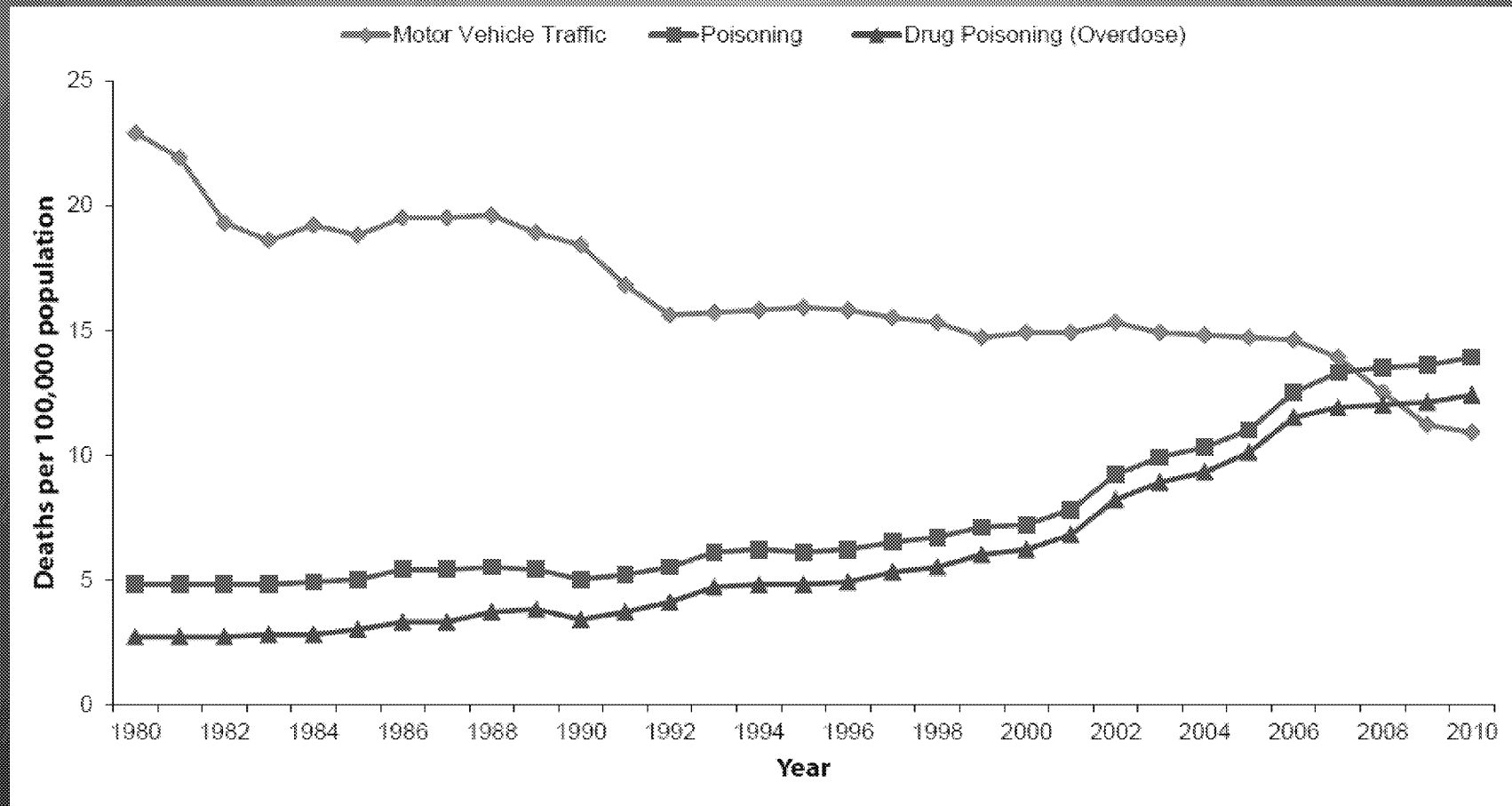
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# U.S. Motor Vehicle Traffic, Poisoning, and Drug Poisoning (Overdose) Death Rates, 1980-2010



Source: CDC National Center for Health Statistics (NCHS) Data Brief, December 2011, updated with 2009 and 2010 mortality data

U.S. Drug Enforcement Administration /  
Operations Division / Office of Diversion  
Control

# The Perfect Storm

- **Industry is producing a wider variety of controlled substance pharmaceuticals and practitioners are prescribing more.**
- **Use of Medicare / Medicaid or insurance to fund drug habits**
- **Information / Electronic era**

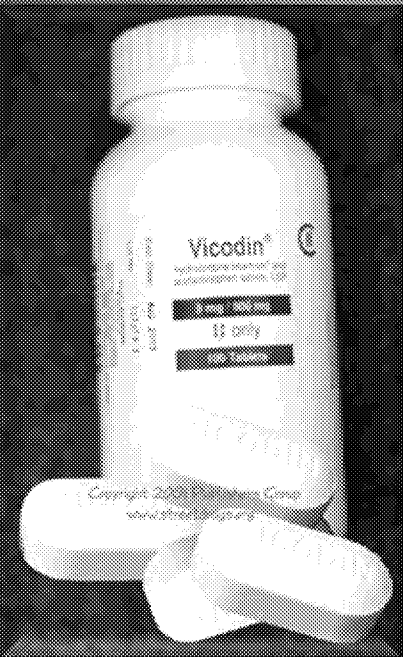
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# Drug Education or not

# What are kids listening to... Eminem?

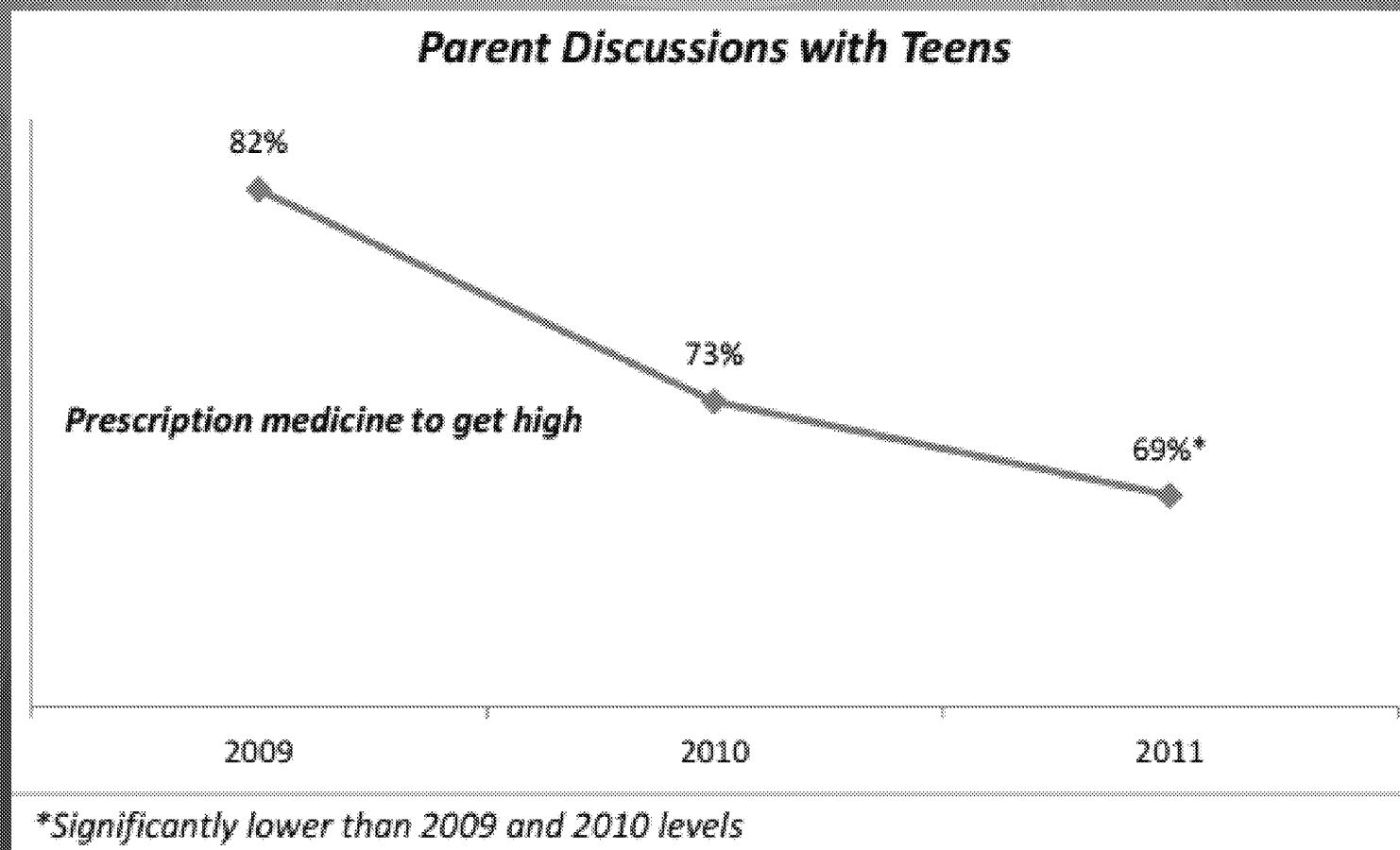
- Rap star Eminem has a Vicodin® tattoo on his arm and a picture of a Vicodin® tablet on one of his CDs





# Partnership Attitudes

Parents are not discussing the risks of abusing prescription drugs



U.S. Drug Enforcement Administration / Operations  
Division / Office of Diversion Control

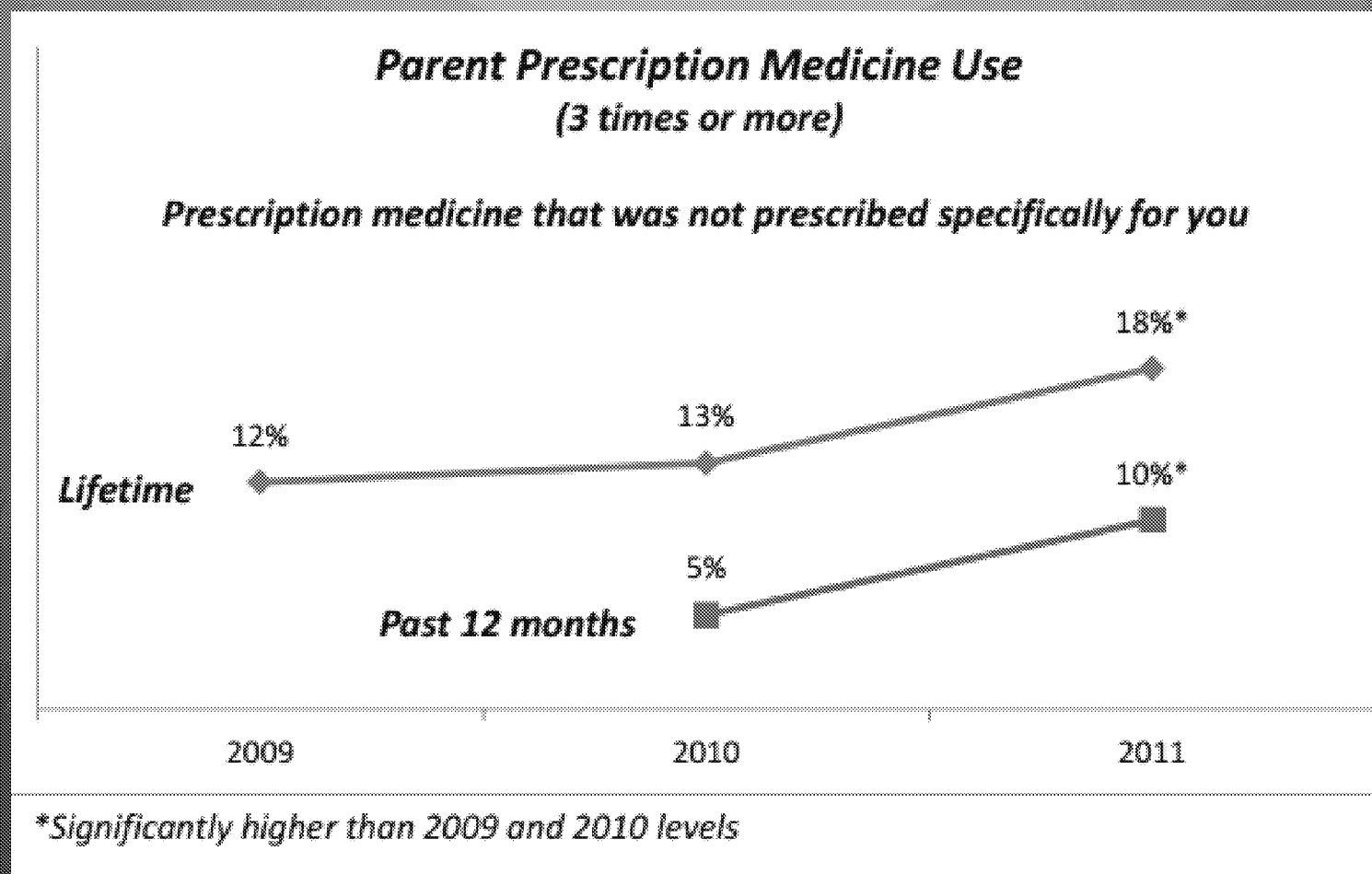
Source: 2011 Partnership Attitude Tracking Study

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# Parent Prescription Diversion

Parents and their abuse of prescription drugs



U.S. Drug Enforcement Administration / Operations  
Division / Office of Diversion Control

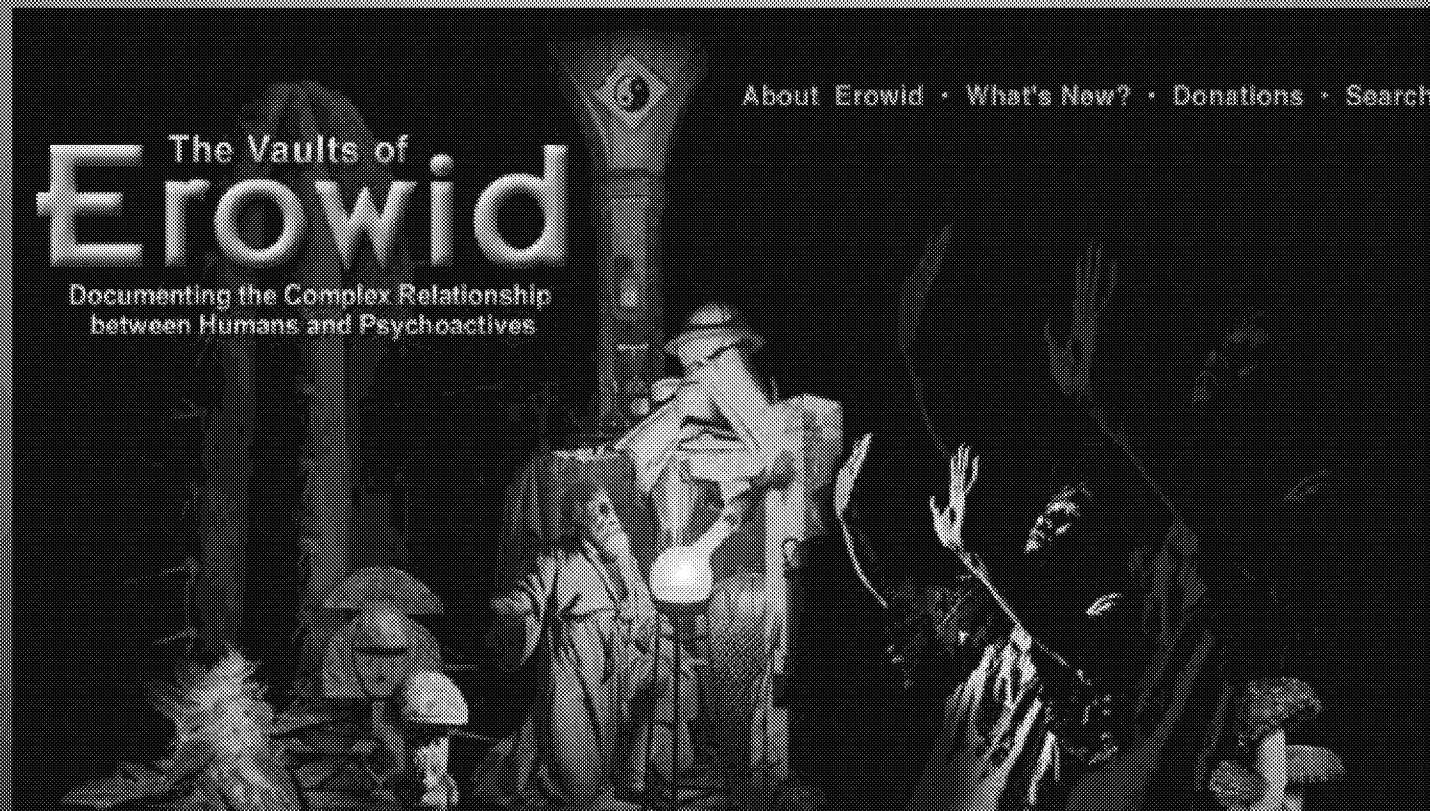
Source: 2011 Partnership Attitude Tracking Study

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# Where do kids get their information from?





# We will not arrest our way out of this problem!!!!

- Enforcement is just as important as....
- Prevention/Education
- Treatment
- TREATMENT!!!!

# ONDCP Strategy

## “Epidemic: Responding To America’s Prescription Drug Abuse Crisis” (Released in April 2011)



- Education
  - Healthcare Provider Education
  - Parent, Youth, and Patient Education
- Tracking and Monitoring
  - Work with states to establish effective PDMPs
  - Support NASPER
  - Explore reimbursements to prescribers who check PDMPs before writing a prescription
- Proper Medicine Disposal
- Enforcement
  - Assist states address doctor shopping and pill mills
  - Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking
  - Expand the use of PDMPs to identify criminal prescribers and clinics



# DEA Response

## Enforcement

- Regulatory/Administrative/Civil/Criminal
- Stepped-up inspection program
- TDS program

## National Take-back Initiative

- Proposed regulations

## Education

- Pharmacist Diversion Awareness Conferences (PDAC)
- Participation in conferences for healthcare professionals
- Registrant conferences

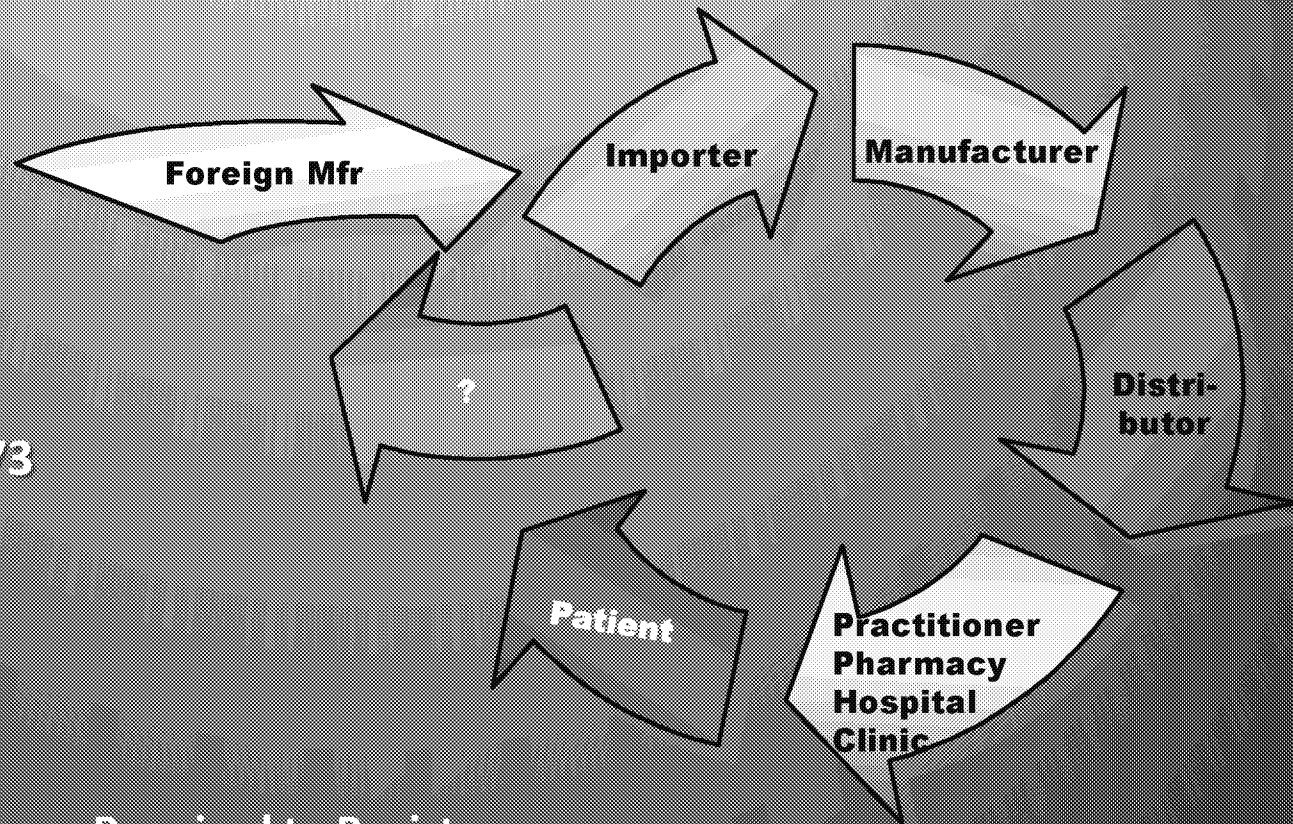


The Controlled Substances Act

**21 United States Code**

# *Closed System of Distribution*

1,469,638 (01/22/13)  
Practitioners 1,149,498  
Retail Pharmacies 68,473  
Hospital/Clinics 15,849



## **Law: 21 USC 822 (a) (1) Persons Required to Register:**

“Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

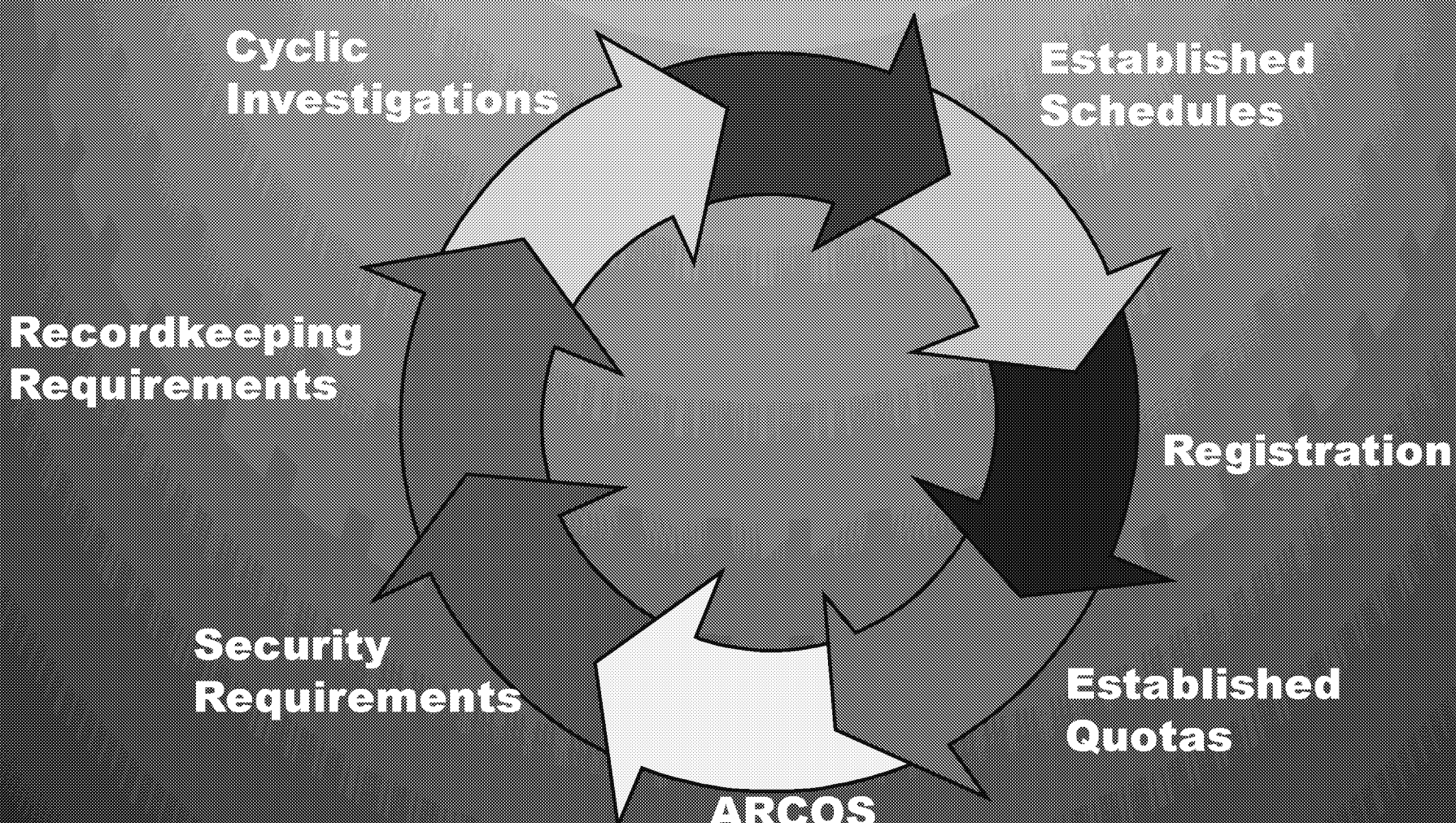
## **Law: 21 USC 822 (a) (2) Persons Required to Register:**

“Every person who dispenses, or who proposes to dispense any controlled substance ...”



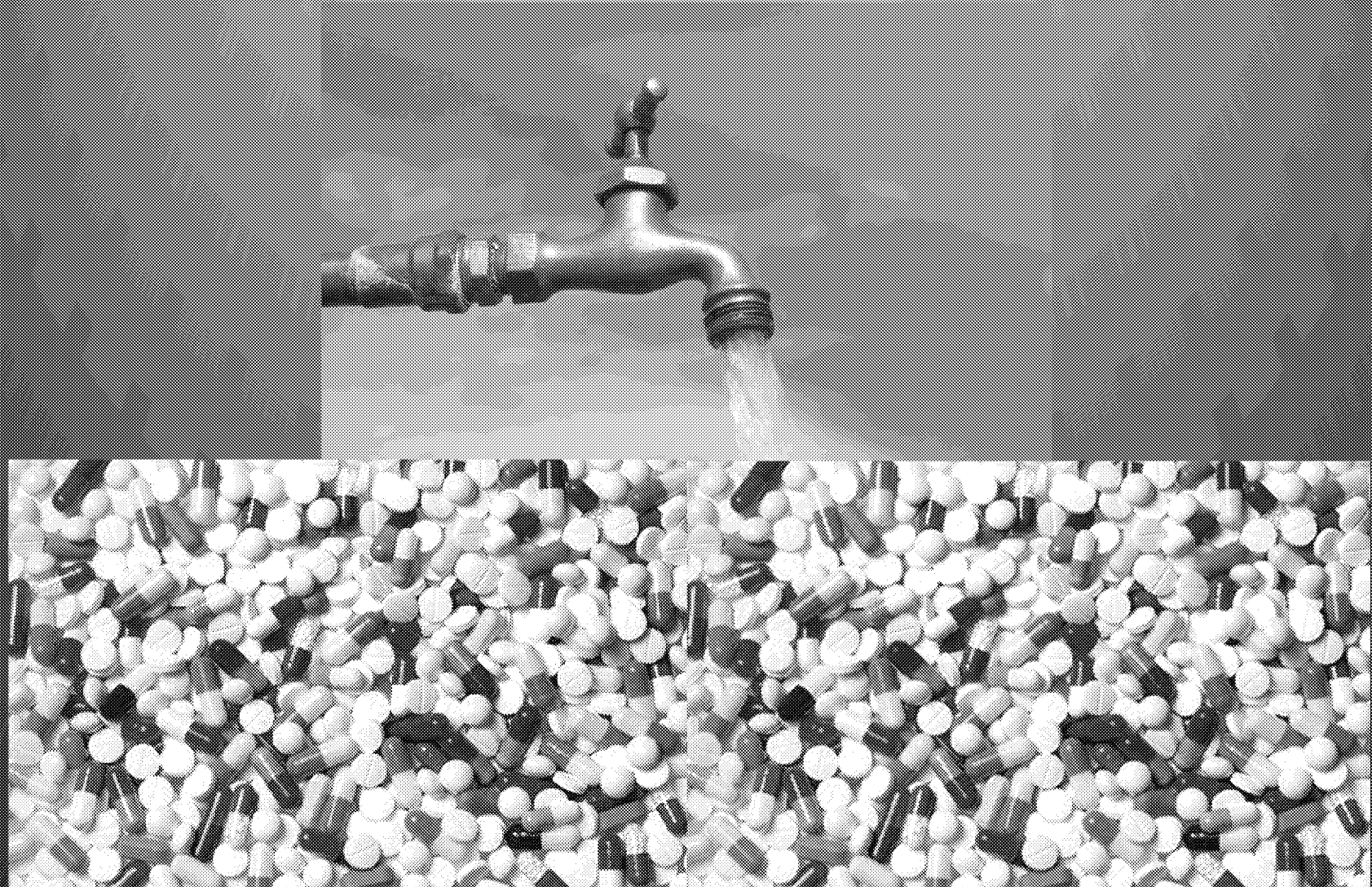


# Closed System of Distribution



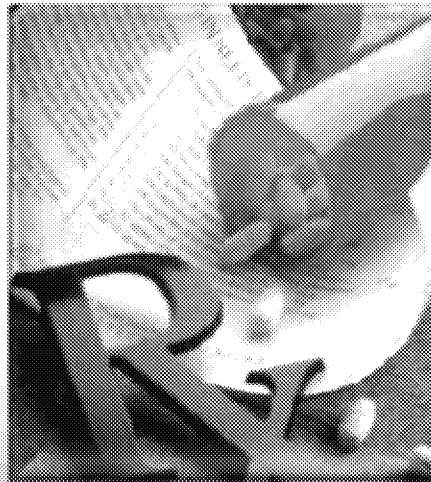


# Cutting off the Source of Supply



# The Controlled Substances Act

## Checks and Balances



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# The Flow of Pharmaceuticals

QUOTAS

21 USC 823(c)(1)  
21 USC 823(d)(1)  
21 CFR 1301.71

21 USC 823(b)(1)  
21 USC 823(e)(1)  
21 CFR 1301.71  
21 CFR 1301.74  
(Suspicious Orders)

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Raw Material

Importers

Imp - Manufacturers

Manufacturers

Dosage Form  
Manufacturers

Dosage Form  
Manufacturers

Smaller Distributors

Wholesalers - Distributors

Hospitals

Pharmacies

Physicians  
(Rx and drugs)

NTPs

21 CFR 1306.04

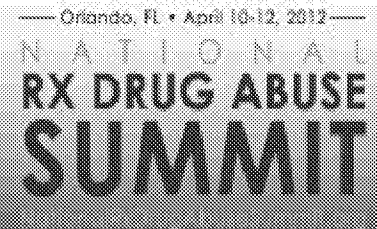
PATIENTS



# Checks and Balances of the CSA and the Regulatory Scheme

- Distributors of controlled substances

*“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” (21 CFR § 1301.74)*





# DEA Distributor Initiative

## **Purpose and format:**

- **Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances**

## **August 2005 – Present:**

- **Briefings to 81 firms with 233 locations**
- **Examples of civil action against distributors:**
  - **Cardinal Health , \$34 million civil fine**
  - **McKesson, \$13.25 million civil fine**
  - **Harvard, \$6 million civil fine**
- **Examples of suspension, surrender or revocation of DEA registration**
  - **Keysource, loss of DEA registration**
  - **Sunrise, loss of DEA registration**



# Drug wholesaler, 2 pharmacies charged in DEA crackdown

By Donna Leinwand Leger, USA TODAY

Updated 15h 4m ago

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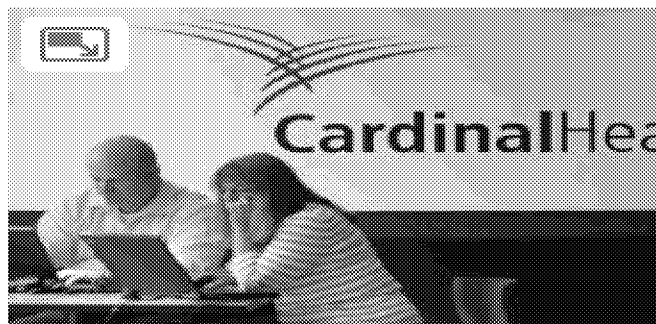
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Federal authorities have expanded their crackdown on painkiller abuse, charging a major health care company and two CVS pharmacies in Florida with violating their licenses to sell powerful pain pills and other drugs.



By Kiyohiro Sato, 2007 AP photo

The DEA suspended Cardinal Health's controlled substances licenses on Friday for the third time in five years.

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The Drug Enforcement Administration linked Cardinal Health to unusually high shipments of the controlled drugs to four pharmacies.

On Friday, the DEA suspended Cardinal's controlled substances license at its Lakeland, Fla., distribution center, which services 2,500 pharmacies in Florida, Georgia and South Carolina.

A federal judge temporarily halted the suspension the same day after Cardinal, a \$1.3 billion company, said it would stop supplying the drugs to the four pharmacies. A hearing on the suspension order was set for Feb. 13 in Washington, D.C.

"We believe the DEA is wrong," CEO George Barrett said on the company's website.

The action comes as the DEA is cracking down on pill mills — rogue doctors and shady pharmacies that divert the highly addictive pills, such as oxycodone, to drug dealers.

"This is still an ongoing investigation," said DEA Special Agent David Melenkevitz, spokesman for the Miami Field Division. "We will be able to provide more information on Monday."

CVS said Saturday it had taken steps with DEA's knowledge to stop filling prescriptions from doctors thought to be prescribing improperly.

"We informed a small number of Florida physicians that CVS/pharmacy will no longer fill the prescriptions they write for Schedule II narcotics," spokeswoman Carolyn Castel said in a written statement. "Distributions of oxycodone to the two Florida stores have decreased by approximately 80% in the last three months compared to the prior three months — we believe in large part due to our action."

In its suspension order, the DEA alleges that Cardinal knew or should have known that

The Company called the DEA action "a drastic overreaction" that would disrupt delivery of critical medications to hospitals and pharmacies.

illegitimate use, Barrett said. Cardinal's internal controls have flagged more than 160 pharmacies in Florida and 350 pharmacies nationwide for "suspicious order patterns," he said. Barrett said the DEA is holding the company responsible for a part of the supply

"At the time we filled these orders, the pharmacies held valid state board of pharmacy and DEA licenses," Barrett said in a call to investors on Friday. "Pharmaceutical distributors do not influence the manufacture of controlled medicines. We do not write prescriptions. We do not dispense controlled medicines, nor do we license pharmacies. Our role is, as a distributor, a critical link in the supply chain between pharmaceutical manufacturers and pharmacies." Cardinal CEO George Barrett

In November 2007, the DEA suspended the license for Cardinal's Auburn, Wash., distribution facility for selling 18 million hydrocodone pills in nine months to retail drugstores. The company sold 605,000 pills to one store in Burlington, Wash., over a seven-month period, the DEA said.





# The DEA Inspection

- **Investigators will identify themselves and produce their official credentials**
- **Investigators will produce, either a**
  - **Notice of Inspection**
  - **Administrative Inspection Warrant**
  - **Search Warrant**

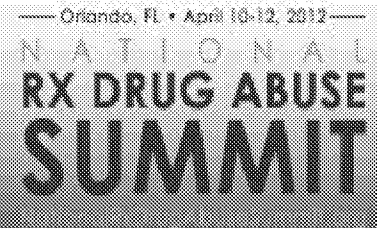
# Checks and Balances

## Under the CSA

- Practitioners

*“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.”* (21 CFR § 1306.04(a))

*United States v Moore* 423 US 122 (1975)

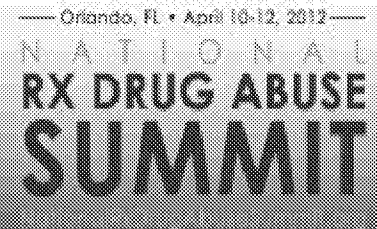




# Checks and Balances Under the CSA

- Pharmacists – The Last Line of Defense

*“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”* (21 CFR § 1306.04(a))



**What can happen when these  
checks and balances collapse  
and diversion occurs?**

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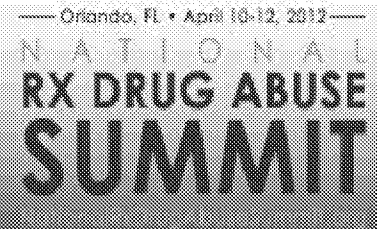


# Large-Scale Diversion

- In 2009, the average purchase for all oxycodone products for all pharmacies in US – 63,294 d.u.
- In 2010, the average was – 69,449 d.u.
- In 2009, the average purchase for all oxycodone products for the top 100 pharmacies in Florida – 1,226,460 d.u.
- In 2010, the average was – 1,261,908 d.u.

# Purchases of Oxycodone 30mg

- In 2009, 44% of all oxycodone 30mg products were distributed to Florida
- In 2010, 43% of all oxycodone 30mg products were distributed to Florida



# Drug Dealers Masquerading as Doctors

## Paul Volkman, Chicago Doctor, Gets 4 Life Terms In Drug Overdose Case



ANDREW WELSH-HUGGINS 02/14/12 06:45 PM ET Associated Press

COLUMBUS, Ohio — A Chicago doctor who prosecutors say dispensed more of the powerful painkiller oxycodone from 2003 to 2005 than any other physician in the country was sentenced Tuesday to four life terms in the overdose deaths of four patients.

Dr. Paul Volkman made weekly trips from Chicago to three locations in Portsmouth in southern Ohio and one in Chillicothe in central Ohio before federal investigators shut down the operations in 2006, prosecutors said. He was sentenced in federal court in Cincinnati.

"This criminal conduct had devastating consequences to the community Volkman was supposed to serve," Assistant U.S. Attorneys Adam Wright and Tim Oakley said in a court filing ahead of Tuesday's hearing.

"Volkman's actions created and prolonged debilitating addictions; distributed countless drugs to be sold on the street; and took the lives of numerous individuals who died just days after visiting him," they said. The 64-year-old Volkman fired his attorneys earlier this month and said he acted at all times as a doctor, not a drug dealer.

"The typical drug dealer does not care how much drugs a client buys, how often he buys, or what he does with his drugs," Volkman said in a 28-page handwritten court filing Monday, maintaining that he did all those things and more for his patients.

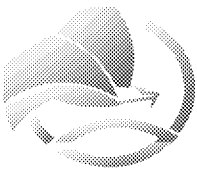
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# Violations?

What happens next.....

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# Notice of Inspection

- **You may refuse the inspection and require an AIW or SW.**
  - **Explain the NOI and provide a copy**
  - **Explain the purpose of the visit**
  - **Request to inspect the registered location and the controlled substance records**
  - **Receipt provided for records obtained**
  - **Conducted between normal business hours**

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# **Administrative Inspection Warrant**

- **Reviewed by an Assistant United States Attorney**
- **Executed by a United States Magistrate Judge**
- **Served with a copy of the AIW**
- **Controlled substances records obtained and a receipt provided**
- **Conducted between normal business hours**

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# *DEA Legal Recourse*

- Administrative

Immediate Suspension Order (ISO)

Memorandum of Agreement (MOA)

Order to Show Cause (OTSC)

- Civil

Fines

- Criminal

Tactical Diversion Squads



# How Do You Lose Your Registration?

## The Order to Show Cause Process

21 USC § 824

- a) Grounds –
  - 1. Falsification of Application
  - 2. Felony Conviction
  - 3. State License or Registration suspended, revoked or denied – no longer authorized by State law
  - 4. Inconsistent with Public Interest
  - 5. Excluded from participation in Title 42 USC § 1320a-7(a) program
- b) AG discretion, may suspend any registration simultaneously with Order to Show Cause upon a finding of Imminent Danger to Public Health and Safety

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# Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!



# The Medicine Cabinet and the Problem of Pharmaceutical Controlled Substance Disposal

# The Problem – Easy Access



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# So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules